

B<sup>2</sup>  
contd.  
~~more insect repellents in the finished cosmetic or dermatological preparations is chosen from the range 0.1 – 15.0% by weight, based on the total weight of the composition.~~

11. The O/W microemulsion composition of claim 5, wherein the total amount of one or more insect repellents in the finished cosmetic or dermatological preparations is chosen from the range 0.5 – 8.0% by weight, based on the total weight of the composition.

✓  
Please add new claims 12 and 13.

- B<sup>3</sup>
12. The O/W microemulsion composition of claim 5, wherein the optional substances which are soluble or dispersible in the oil phase or water phase is an emulsifier which does not have the properties of emulsifier A.
13. The O/W microemulsion composition of claim 12, wherein the emulsifier which does not have the properties of emulsifier A is a W/O emulsifier.

#### REMARKS

Claims 5-13 are now pending. It is believed that no new matter has been added. Claims 5, 6 and 9-11 have been amended to address the examiner's 35 U.S.C. 112, second paragraph concerns. Claims 5-13 have been amended to delete reference to O/W **macroemulsions**. Claim 5 has also been amended to include a lower limitation for the amount of glycerol. Claims 12 and 13 have been added to incorporate the additional range limitations which were deleted from claim 5.

Note that claims referred to below in the response to the examiner's rejections refer to the claims as amended.

#### **35 U.S.C. 112, second paragraph rejections**

It is believed that the amendments to the claims address the first two issues raised by the examiner in her previous office action.

The applicants' respectfully present that the modified claim language for the "emulsifiers which does not have the properties of emulsifier A" is indefinite because the term "emulsifier" has a defined meaning within the art and because one of ordinary skill in the art would be able to determine whether an emulsifier possessed the properties defined for emulsifier A or not.

If the examiner is uncomfortable with the specific language of the claim or the "scope of the claim", she is reminded that MPEP 2173.04 states that "Breadth of a claim is not to be equated with indefiniteness" (see also *in re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971)) and that MPEP 2173.02 states that:

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, ***not whether more suitable language or modes of expression are available.*** When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. ***Examiners are encouraged to suggest claim language to applicants to improve clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.***

While the applicants' appreciate the suggested amended claim language, accepting such an amendment would result in a cumbersome Markush group at best and possibly an indefinite claim or a reduction of scope (in light of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*) at worst.

### ***35 U.S.C. 102(e) rejection***

Claims 5-13 were rejected as being anticipated by the examiner over Kaplan (U.S. Patent 5,989,529) or McShane et al. (U.S. Patent 6,099,825).

Kaplan or McShane et al. no longer anticipate the applicants' claims as amended as the claims are now directed toward O/W microemulsions whereas Kaplan or McShane et al. are directed toward emulsions (macroemulsions) - see also definition of microemulsion and emulsions (macroemulsions).

### ***35 U.S.C. 103(a) rejection***

Claims 5-13 were rejected as being obvious over Hart et al. (U.S. Patent 3,970,584).

Claims 5-13 were rejected as being obvious over Randen (U.S. Patent 4,816,256) or Knowles, Jr. et al. (U.S. Patent 5,575,988) or Thomas et al. (U.S. Patent 5,610,130) in view of Kaplan or McShane et al., *ibid.*

Of the four primary reference cited above, three (i.e. Hart et al., Randen and Knowles, Jr. et al.) differ from the applicants' invention in that they are not directed toward microemulsion compositions. Each of the four primary references do not teach the addition of glycerol.

Kaplan and McShane et al. disclose the use of glycerol but only in the context of being a generic additional ingredient for their emulsion (macroemulsion) composition. Given the differences between microemulsions and emulsions, Kaplan and McShane et al. do not provide the motivation or suggestion to substitute or add glycerol to the microemulsion compositions of Thomas et al.

***Miscellaneous***

An Information Disclosure Statement has been submitted with this response which discloses references cited from the European Search Report.

***Closing***

Early and favorable action is earnestly solicited.

Respectfully submitted,  
NORRIS MCLAUGHLIN & MARCUS, P.A.

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HCL:vif

Attachments: Copy of definition of "microemulsion" and "emulsion (macroemulsion)"  
Clean copy of claims showing amendments made

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**CERTIFICATE OF MAILING**

I hereby certify that the foregoing Preliminary Amendment is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Hon. Assistant Commissioner for Patents, Washington, D.C. 20231, on the date indicated below:

Date: **4 February 2002**

By Howard C. Lee  
Howard C. Lee

## Microemulsion: A Definition

A microemulsion is a thermodynamically stable dispersion of one liquid phase into another, stabilized by an interfacial film of surfactant. This dispersion may be either oil-in-water or water-in-oil. Microemulsions are typically clear solutions, as the droplet diameter is approximately 100 nanometers or less. The interfacial tension between the two phases is extremely low.

Emulsions (or macroemulsions) are in contrast unstable, the suspended droplets will eventually agglomerate and the dispersed phase will phase separate. Emulsion droplet sizes are much larger, typically one micron or more, resulting in a cloudy or milky dispersion. The nature of an emulsion may depend on the order of mixing of the ingredients and the amount of energy put into the mixing process. The final microemulsion state will not depend on order of mixing, and energy input only determines the time it will take to reach the equilibrium state.

Microemulsions are two phase systems, in contrast to micellar solutions, which may be considered one phase.

For books on microemulsions and their applications, click [here](#).

For more information on surfactants, see the [Surfactants Virtual Library](#).

**CLEAN COPY OF CLAIMS SHOWING AMENDMENTS MADE**

5. An **[oil-in-water (O/W) macroemulsion or]** oil-in-water (O/W) microemulsion composition, **comprising:**
- (a) **[comprising]** at least one emulsifier (emulsifier A), **[chosen] selected** from the group **consisting** of emulsifiers having the following properties
    - (i) their lipophilicity is either dependent on the pH inasmuch as an increase or decrease in pH results in an increase or decrease in lipophilicity, it being unimportant which of the two possibilities of change in the lipophilicity is effected by the increase or the decrease in the pH, and/or
    - (ii) their lipophilicity is dependent on the temperature inasmuch as the lipophilicity increases with increasing temperature and their hydrophilicity increases with decreasing temperature,
  - (b) glycerol in an amount up to 5% by weight based on the total weight of the composition,
  - (c) **[also]** optionally, **[further]** substances which are soluble or dispersible in the oil phase or the water phase, **[including those chosen from the group of emulsifiers not covered by the definition of emulsifier A, in particular those which act primarily as W/O emulsifiers,] and**
  - (d) an effective amount of one or more insect repellents.
6. The **[O/W macroemulsion or]** O/W microemulsion composition of claim [1] 5, wherein the emulsifier A or the emulsifiers A is or are present in concentrations of 0.01 – 20% by weight based on the total weight of the composition.
7. The **[O/W macroemulsion or]** O/W microemulsion composition of claim 6, wherein the emulsifier A or emulsifiers A is or are present in concentrations of 0.05 - 10% by weight, based on the total weight of the composition.

8. The **[O/W macroemulsion or]** O/W microemulsion composition of claim 6, wherein the emulsifier A or emulsifiers A is or are present in concentrations of 0.1 - 5% by weight, based on the total weight of the composition.
9. The **[O/W macroemulsion or]** O/W microemulsion composition of claim [1] 5, wherein the insect repellent(s) is/are chosen from the group consisting of ethyl 3-(N-acetyl-N-butylamino)propionate, N,N-diethyloctanamide, N,N-diethyl-m-toluamide.
10. The **[O/W macroemulsion or]** O/W microemulsion composition of claim [1] 5, wherein the total amount of one or more insect repellents in the finished cosmetic or dermatological preparations is chosen from the range 0.1 – 15.0% by weight, based on the total weight of the composition.
11. The **[O/W macroemulsion or]** O/W microemulsion composition of claim [1] 5, wherein the total amount of one or more insect repellents in the finished cosmetic or dermatological preparations is chosen from the range 0.5 – 8.0% by weight, based on the total weight of the composition.
12. The O/W microemulsion composition of claim 5, wherein the optional substances which are soluble or dispersible in the oil phase or water phase is an emulsifier which does not have the properties of emulsifier A.
13. The O/W microemulsion composition of claim 12, wherein the emulsifier which does not have the properties of emulsifier A is a W/O emulsifier.